APPENDIX I SUMMARY OF SAFETY AND EFFECTIVENESS

For

Eclipse Total Ankle Implant

1. **Submitter:**
Kinetikos Medical, Inc.
6005 Hidden Valley Rd. Suite 180
Carlsbad, CA 92011

Contact Person:
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V.P., Quality Assurance
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6005 Hidden Valley Road Suite 180
Carlsbad, CA 92011
(760) 448 1706 FAX (760) 448 1739

NOV 2 2 2006

Date Prepared: June 15, 2006

2. **Proprietary Name:** Eclipse Total Ankle Implant
Common Name: Ankle Prosthesis
Classification Name Ankle joint metal/polymer semi-constrained
Regulatory Class: Cemented prosthesis; Class II, per 21 CFR 888.3110
Device Product Code: 87 HSN

3. **Predicate or legally marketed devices which are substantially equivalent:**

-Depuy Agility Total Ankle Orthopedic Implant (K020541) cleared May 20, 2002

4. **Description of Device**
The Eclipse Total Ankle implant is intended for use in total ankle joint replacement arthroplasty. The system consists of various size range components to accommodate variations in human ankle anatomy.

Materials: -Cobalt Chrome, per ASTM F75, with Titanium Plasma Spray Coating per ASTM 1580 (Tibia Plates / Talar components)
-U.H.M.W.Pe., per ASTM 648-00 (Bearing)
-Titanium Alloy per ASTM F-136 (Bone screws)

Function: The Eclipse Total Ankle system functions as a replacement for the ankle joint.

5. **Intended Use**
The Eclipse Total Ankle replacement system is intended for prosthetic replacement of the tibio-talar joint in patients effected with severe rheumatoid, post-traumatic, or degenerative arthritis. It is also intended for revision of prior ankle surgery, and is intended for use with bone cement. The Eclipse Total Ankle replacement system is contraindicated for patients with:
-active sepsis or infection
-insufficient bone or osteonecrosis
-insufficient blood supply such that healing activity may be compromised
-Charcot's neuropathy or other peripheral neuropathy
-age, weight or activity levels that introduce unnecessary risk of failure
-insufficient bone or musculature such that proper component positioning or alignment is not possible.

6. **Comparison of technological characteristics of the device to predicate and legally marketed devices:**
There are no significant differences between the Eclipse Total Ankle Implant and other total ankle joint replacement systems currently being marketed which would adversely affect the use of the product. The Eclipse Total Ankle Implant employs the same materials and basic mechanical features as the predicate, legally marketed device specified in section 3 (DePuy *Agility* total ankle arthroplasty system).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Kinetikos Medical, Inc.
% Mr. John G. Spampinato
Vice President, Quality Assurance
6005 Hidden Valley Road, Suite 180
Carlsbad, California 92011

NOV 2 2 2006

Re: K061749
Trade/Device Name: Eclipse Total Ankle Implant
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSN
Dated: October 30, 2006
Received: October 31, 2006

Dear Mr. Spampinato:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Eclipse Total Ankle

Indications For Use:

The Eclipse Total Ankle replacement system is intended for prosthetic replacement of the tibio-talar joint in patients affected with severe rheumatoid, post-traumatic, or degenerative arthritis. It is also intended for revision of prior ankle surgery, and is intended for use with bone cement.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K061749